

## **REMARKS**

Claims 1-11 and 15-24 are pending in the case, with claims 1 and 2 being amended and claims 15-24 being newly presented.<sup>1</sup> Examiner has agreed that the arguments presented on appeal were persuasive and has withdrawn the previous rejections. The Official Action mailed May 2, 2007 presents four new grounds of rejection of previously pending claims 1-11, each of which is traversed hereinbelow.<sup>2</sup> In order to streamline prosecution, the present Response focuses on certain distinctions which are submitted to be sufficient to overcome the rejections. Applicant does not waive any other argument available for patentability of any of the claims over the references cited by Examiner to support the rejections, and reserves the right to present such arguments should that prove necessary.

### **Jagger et al U.S. Patent No. 4,781,692**

Examiner asserts that claims 1-5, 7 and 9 are anticipated by Jagger et al U.S. Patent No. 4,781,692. Not so. As Examiner will note, the claims require a "blocking means" which is for "blocking the tip protector opening". There is no such means in the Jagger reference. Examiner acknowledges element 106 as the tip protector and then points to element 104 thereof as such a means, but that is clearly in error. Element 104 of the Jagger reference is a flexible plastic tubular catheter. There is nothing in that tubular

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<sup>1</sup> Claims 8, 10 and 11 were previously withdrawn by the prior Examiner but have been restored to this case by the present Examiner and were examined in the present Official Action.

<sup>2</sup> Examiner also objected to claims 1, 6, and 7. The objections are submitted to be resolved by the minor amendments made to claim 1. Specifically, "top" has been corrected to "tip". With respect to claims 6 and 7, it is submitted that the "blocking means" and "impeding means" thereof are clearly seen in claim 1 which recited both "means coupled to the tip protector for blocking" and "means coupled to the needle cannula shaft for impeding" which are readily understood to be the respective blocking and impeding means. The objection to claims 6 and 7 is thus not seen as appropriate. Rather than further prolong prosecution of this case which is close to six years long already, claim 1 has been amended to recite that those means are, respectively, "blocking means" and "impeding means" as they have always been understood as such.

member that can be seen as "blocking" the opening of rigid plastic housing 106 to which it is connected and into which the stylet 100 is partially withdrawn. Indeed, as readily seen in Fig. 5 of the Jagger reference, the opening into housing 106 is unimpeded by anything other than the distal end of the stylet that extends therethrough, notwithstanding that the stylet is fully retracted. Hence, catheter 104 could never "block" the opening, inasmuch as the stylet is always in the way.

By contrast, the specification of the present application makes clear that the blocking means, which is shown in a preferred embodiment as a tab which pivots into the path of the needle after the needle is withdrawn, actually serves to block the tip protector opening "so as to enclose the distal point of the needle cannula within the tip protector" (in the words of the claims). Such "blocking" necessarily involves creating a physical barrier to the needle tip from passing back out of the tip protector once withdrawn. As mentioned, even when the stylet is fully retracted, the tip of the stylet in the Jagger reference protrudes beyond the housing 106 and into the catheter 104 at the junction between the catheter and housing. Hence, there is no blocking so as to enclose the tip, as it is not actually enclosed in the housing 106. Nor is there anything in the Jagger reference which appears to provide the claimed means or its function. Hence, while there are also many other differences between the claims and what is disclosed in the Jagger reference, for at least the reasons explained above, the Jagger reference cannot anticipate any of the claims. Hence, it is respectfully submitted that the rejections based on the Jagger reference are in error and should be withdrawn.

**Plassche U.S. Patent No. 5,300,045**

Examiner next cites Plassche U.S. Patent No. 5,300,045 as allegedly anticipating claims 1 and 3-10. Again, not so. Among other things, the claims require a "gasket coupled to the tip protector base". The gasket is thus a separate component placed into or added to the base of the tip protector. It is not merely a hole pre-formed or punched into a housing through which a shaft can pass. Yet, that is all the more that is shown in the Plassche reference. In that regard, Examiner points to the proximal opening of guard body 38 as a gasket. There is no technical or logical basis to assert that a hole in a housing is a gasket. Not only is that opening merely an inherent aspect of the guard body during its molding, it cannot serve as a gasket as that term is commonly and readily understood.

The gasket not only surrounds the needle cannula shaft, but also defines an opening for the needles shaft to pass through, which the specification makes clear is almost identical to the circumference of the needle shaft. As readily understood by any ordinarily skilled artisan, such a gasket thus involves creating a close fit to needle shaft so as to provide not only a passage therethrough, but something akin to a seal therealong. That is not possible with just any opening in any housing. Rather, gaskets are separate components or structure placed into or added to another component, such as a housing, to create a close and tight fit with the element passing through the gasket. The opening at the back end of the guard body of the Plassche reference is nowhere suggested to provide such a result, nor would it be expected to create such a tight fit between a plastic housing and a shaft to be slid through that opening. The tolerances otherwise required would create severe manufacturing issues. Moreover, the resulting drag forces created would be

significant and problematic, both in terms of assembly of the device, and in terms of use in the field.

Thus, while there are also many other differences between the claims and what is disclosed in the Plassche reference, for at least the reason explained above, the Plassche reference cannot anticipate any of the claims. Hence, it is respectfully submitted that the rejections based on the Plassche reference are in error and should be withdrawn.

**Woehr et al U.S. Patent No. 6,117,108**

Examiner next cites Woehr et al U.S. Patent No. 6,117,108 as allegedly anticipating claims 1, 2 and 6-9. However, for at least the same reason explained above that the Plassche reference does not anticipate the claims, neither does the Woehr reference. Again, among other things, the claims require a "gasket coupled to the tip protector base". The gasket is thus a separate component placed into or added to the base of the tip protector. It is not merely a hole pre-formed or punched into a wall through which a shaft can pass. Yet, that is all the more that is shown in the Woehr reference. In that regard, Examiner points to opening 58 of proximal wall 54, for example, as a gasket. Examiner will note, however, that the clip of the Woehr reference is a unitary device, so it has only one piece, namely, a metal piece that is folded and punched to have the structure and shape shown therein. There is no separate component placed into or added to the wall; rather that hole is part of the wall. There is no technical or logical basis to assert that a hole in a wall is a gasket. Not only is that opening merely an inherent aspect of the wall created by punching the metal, it cannot serve as a gasket as that term is commonly and readily understood.

The gasket not only surrounds the needle cannula shaft, but also defines an opening for the needles shaft to pass through, which the specification makes clear is almost identical to the circumference of the needle shaft. As readily understood by any ordinarily skilled artisan, such a gasket thus involves creating a close fit to needle shaft so as to provide not only a passage therethrough, but something akin to a seal therealong. That is not possible with just any opening punched into a wall, and, indeed, is expressly not what the opening 58 is intended to do when the clip is in the ready state as described in the Woehr reference. Rather, there, the hole is intended to let the needle freely pass through it until the wall cants when the clip fires. Then, the perimeter of the hole may grip the shaft of the needle by biting into the metal thereat. Clearly, not a gasket in any sense of the word.

Nor is the opening in the wall of the clip of the Woehr reference anywhere suggested to provide, and it likely would not be expected to create, a tight fit between the clip opening and the needle shaft, as indeed, the Woehr reference wants them to be freely slidable in the ready state. Were it otherwise, the drag forces created would be significant and problematic.

Thus, while there are also many other differences between the claims and what is disclosed in the Woehr reference, for at least the reason explained above, the Woehr reference cannot anticipate any of the claims. Hence, it is respectfully submitted that the rejections based on the Woehr reference are in error and should be withdrawn.

**Brimhall U.S. Patent No. 6,224,569**

Finally, Examiner rejects claims 1-10 as allegedly anticipated by Brimhall U.S. Patent No. 6,224,569, and claim 11 as allegedly obvious over Brimhall in view of

Shinohura U.S. Patent No. 4,551,138. While Applicant does not waive the right to argue the merits of the rejections, it is currently considered unnecessary to do so. Rather, Brimhall is submitted not to be prior art in any event, and so should be withdrawn as a basis for any rejection. Without Brimhall, the rejections fail as a matter of law. That is the situation here.

Brimhall did not issue until May 1, 2001, which is well after the effective filing date of the present application, which is entitled to the December 30, 1999 filing date of the parent case, U.S. Patent No. 6,322,537. Brimhall may thus only be considered as "prior art" whether for an anticipation rejection or an obviousness rejection due to 35 USC § 102(e) which makes the effective filing date of a U.S. patent the date by which it may be considered as a reference. MPEP 2136.02. Brimhall was filed September 24, 1999, which is prior to the December 30, 1999 effective filing date of the present application. Even in such instances, however, an applicant may submit a declaration "to establish prior invention of the subject matter of the rejected claims prior to the effective date of the reference or activity on which the rejection is based." 37 CFR § 1.131(a); MPEP 715. *Accord, In re Eickmeyer*, 202 USPQ 655, 660 (CCPA 1979) ("If the 131 affidavit demonstrates that the applicant's date of invention is earlier than the effective date of the reference, the reference is eliminated as support for the rejection.").

Applicant submits that he had his invention before the filing date of Brimhall. To that end, attached hereto is the Declaration of Joseph J. Chang Under 37 CFR § 1.131 which establishes that Mr. Chang, who is the sole inventor named in the present application, invented the claimed subject matter before the filing date of Brimhall. Under the circumstances, Brimhall is antedated and may not be relied upon by Examiner to

support the rejections. Hence, the rejections based on Brimhall alone or Brimahll in combination with Shinohura cannot stand. Withdrawal of those rejections is thus respectfully solicited.

### **New Claims**

New claims 15-24 are presented herewith and are submitted to be patentable based on the specific structural features set forth therein and which are submitted to be lacking in the Jagger, Plassche and Woehr references (Brimhall is submitted not to be prior art and so is not currently addressed further).

### **Conclusion**

In view of the foregoing amendments and comments, it is respectfully submitted that the application is in condition for allowance. Accordingly, a formal Notice of Allowance is respectfully solicited.

Applicant has undertaken to respond to all issues raised in the Official Action. In the event that any issues remain outstanding, Examiner is invited to contact the undersigned to expedite prosecution of this application.

The fee for a two month extension and for added claims is being paid concurrently herewith. No other fee is believed due with this paper. If any fee is due or

is not otherwise properly paid, the Commissioner is authorized to charge any such fee or credit any overpayment to Deposit Account No. 23-3000.

Respectfully submitted,  
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